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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,777	03/09/2004	Eija Pirhonen	01942-00019	1657

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BANNER & WITCOFF, LTD.  
28 STATE STREET  
28th FLOOR  
BOSTON, MA 02109-9601

EXAMINER

DESAI, ANAND U

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 09/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/796,777	Applicant(s) PIRHONEN ET AL.	
	Examiner Anand U. Desai, Ph.D.	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-14,21 and 24-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-14,21 and 24-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>20050713</u> . | 6) <input type="checkbox"/> Other: _____  |

2

### **DETAILED ACTION**

1. This office action is in response to Amendment filed on June 20, 2005. Claims 3, 4, 15-20, 22, and 23 have been cancelled. Claims 1, 2, 5-14, 21, and 24-35 are currently pending and are under examination.

#### **Withdrawal of Rejections**

2. The rejection of claims 1, 5-14, and 21, 24-35 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

3. The rejection of claims 1, 6-8, 10-12, 21, 24-26, 28, 29, and 31-35 under 35 U.S.C. 102(b) as being anticipated by Eitenmuller et al. (U.S. Patent 4,610,692) is withdrawn.

4. The rejection of claims 5, 9, 13, 14, and 27 under 35 U.S.C. 103(a) as being unpatentable over Eitenmuller et al. (U.S. Patent 4,610,692) in view of Pirhonen et al. (U.S. Patent Publication 2003/0104029 A1) and Santos, E. et al. (IDS document : AQ ; J. Biomed. Mater. Res. 41(1): 87-94 (1998)) is withdrawn.

5. The rejection of claim 30 under 35 U.S.C. 103(a) as being unpatentable over Eitenmuller et al. (U.S. Patent 4,610,692) in view of Pirhonen et al. (U.S. Patent Publication 2003/0104029 A1) and Santos, E. et al. (IDS document : AQ ; J. Biomed. Mater. Res. 41(1): 87-94 (1998)) and further in view of Hall (U.S. Patent 6,730,129 B1) is withdrawn.

#### **Maintenance of Objections and Rejections**

##### ***Specification***

6. The disclosure is objected to because of the following informalities:

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7. On page 1, the comma after the word, "recent" in paragraph 6 appears to be misplaced.

Suggest placing it after the word, "years".

8. The second sentence in paragraph 6, appears to require a plural verb, "have" as opposed to the singular form, "has".

9. In paragraph 16, suggest spelling the word, "recombinant" to describe the abbreviation "rBMPs".

Appropriate correction is required.

#### *Claim Objections*

10. Claims 2, and 28 are objected to because of the following informalities:

11. In claim 2, "of according" is grammatically awkward. Suggest removing the word, "of".

12. In claim 33, "anorganic" is misspelled.

Appropriate correction is required.

#### *Claim Rejections - 35 USC § 112*

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 29, 30, 31, and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

15. In claim 29, what is glass material? Claim 21 recites "glass" accordingly claim 29 fails to further limit. There is insufficient antecedent basis for this limitation in the claim.

16. Claim 30 recites the limitation "metal". There is insufficient antecedent basis for this limitation in the claim.

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17. Claim 31 recites the limitation "polymer". There is insufficient antecedent basis for this limitation in the claim.

18. Claim 32 fails to further limit the claimed invention.

19. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

20. Claims 8, and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a bone grafting material comprising at least one bioactive agent, wherein the agent is a **polypeptide** having bioactivity.

To satisfy the written description requirement, the specification must describe the invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. The specification does not describe the structure, that is amino acids in the various polypeptides that can be altered without affecting the function of a specific polypeptide. For one to be in possession of the claimed invention, the inventor would have to know the functional consequences of structural alterations. Thus due to the limited predictability in the art, a skilled artisan would not find adequate support for any **polypeptide** as disclosed in claims 8, and 26 in the specification.

***Claim Rejections - 35 USC § 103***

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

22. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

23. Claims 1, 2, 5-14, 21, 24, 25, 26, 27, 28, 29, and 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pirhonen et al. (U.S. Patent 6,926,903 B2) in view of Santos, E. et al. (IDS document: AQ; J. Biomed. Mater. Res. 41(1) : 87-94 (1998)).

Pirhonen et al. disclose a resorbable polymer composition that is useful in the manufacture of medical implants, wherein the composition comprises a base material including a polymer matrix or resorbable polymer or copolymer, and N-methyl-2-pyrrolidone (NMP), wherein NMP is present in an amount imparting osteogenic properties for the composition (see U.S. Patent '903, particularly claims 1, and 7). Pirhonen et al. does not disclose a porous carrier comprising glass or ceramic as a substrate for bone formation.

Santos, E. et al. disclose a porous Si-Ca-P xerogel glass that can be used to provide a bioactive substrate for bone formation (see page 88, last paragraph of Introduction), and can be used as a vehicle for the controlled release of bioactive factors, such as BMP-2, a member of the BMP family (see page 93, last paragraph of Discussion section). Santos, E. et al. disclose the use of a polymer carrier such as collagen to induce bone formation. The polymer carrier regulates the release of the osteogenic protein (see page 87-88, 4<sup>th</sup> paragraph of Introduction).

One would have been motivated to produce a composition comprising a porous carrier of glass material as disclosed by Santos, E. et al. and at least one osteogenic pyrrolidone as disclosed by Pirhonen et al., along with a bone morphogenetic protein, because of the need to ensure an effective local concentration of an osteogenic composition during bone formation. Furthermore, one would have been motivated to manufacture a porous carrier comprising a glass material/polymer composite to regulate the release parameters of the osteogenic substances, N-methyl-2-pyrrolidone, and BMP-2. Therefore, it would have been obvious to the person having ordinary skill in the art to manufacture a composition comprising a porous carrier of glass material/polymer composite, N-methyl-2-pyrrolidone, and a bone morphogenetic protein, such as BMP-2, since both Pirhonen et al. and Santos, E. et al. disclose the osteogenic properties of N-methyl-2-pyrrolidone, and BMP-2, respectively (current application, claims 1, 2, 5-14, 21, 24, 25, 26, 27, 28, 29, and 31-35).

24. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pirhonen et al. (U.S. Patent 6,926,903 B2) in view of Santos, E. et al. (IDS document: AQ; J. Biomed. Mater.

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Res. 41(1): 87-94 (1998)) as applied to claims 1, 2, 5-14, 21, 24, 25, 26, 27, 28, 29, and 31-35 above, and further in view of Hall (U.S. Patent 6,730,129 B1).

Hall disclose the use of a biocompatible material made of a metal, titanium, for implant in bone that is coated with a calcium phosphate substance and at least one bone growth stimulating substance (see U.S. Patent '129, particularly claim 25).

One would have been motivated to use a metal scaffold, because the scaffold provides a wider range and choice of implants to satisfy different applications to facilitate various bone growths, such as soft bones, and hard bones (U.S. Patent '129, col. 2, lines 53-56). Therefore it would have been obvious to the person having ordinary skill in the art to manufacture an implant comprising a metal scaffold, with a porous carrier of calcium phosphate and N-methyl-2-pyrrolidone along with BMP-2 to increase osteogenic properties of the implant (current application, claims 1, 2, 5-14, 21, and 24-35).

### *Conclusion*

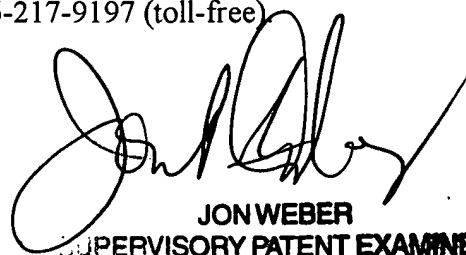
25. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 7:00 a.m. - 3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 2, 2005



**JON WEBER**  
SUPERVISORY PATENT EXAMINER